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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,201	12/19/2001	Mary K. Crow	5983/1H567US1	5071

7590 03/25/2003
DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,201	CROW, MARY K.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to methods for identifying a gene associated with a disease, classified in class 435, subclass 6.
 - II. Claims 4-9, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said methods utilizes nucleic acid analysis, classified in class 435, subclass 6.
 - III. Claims 7-9, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said method utilizes protein analysis, classified in class 435, subclass 7.1.
 - IV. Claims 10-11, drawn to methods of treatment which utilize anti-sense technology, classified in class 514, subclass 44.
 - V. Claims 10-11, drawn to methods of treatment which utilize antibodies or proteins, classified in class 530, subclass 350+, for example.
 - VI. Claims 12-14 and 15-18, drawn to methods for identifying an individual at risk or suffering from a complex disease, wherein said method utilizes antibody analysis, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they either have different functions, that is are directed towards different goals of gene identification, disease diagnosis, or disease treatment OR they utilize different method steps and reagents. For example, the methods of groups II, III, and VI are considered to be unrelated because, while they have a similar goal of disease diagnosis, they have different modes of operation because they utilize different reagents and methodologies in the detection of complex disease. Likewise, while inventions IV and V are similar because they involve treatment of disease, they are unrelated because the ends used to achieve this goal is very different, that is the use of antisense technology versus the administration of a polypeptide or antibody. Thus, the groups are all unrelated.

Further Restriction Requirement

Each of the groups outlined above is generic to and contains claims reciting a multitude of different inventions, wherein each invention is considered to be a one of the many complex diseases listed in the claims. The detection of genes related to, the diagnosis of, and the treatment of each of these diseases is distinct from one another because they have a wide variety of etiologies, symptomologies, and treatments. A reference for one would not be a reference for the other. Applicant is to elect a SINGLE disease for prosecution. Generic claims will be examined to their full scope, but for the claims which recite more than one disease, examination will be restricted to the single elected invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI, and all of the different disease, require

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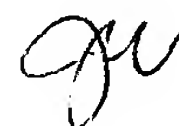
different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

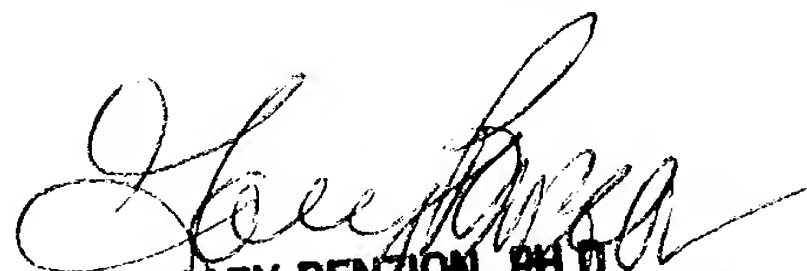
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Einsmann
Examiner
Art Unit 1634

March 22, 2003



GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600